TEXAS DEPARTMENT of HEALTH
Bureau of Food and Drug Safety
Drugs and Medical Devices

MINIMUM STANDARDS FOR NARCOTIC TREATMENT PROGRAMS

(25 Texas Administrative Code, §§ 229.141 – 229.153)

Section:

§229.141. General Provisions. The purpose of the sections in this chapter is to provide assurance that facilities holding an approved narcotic drug permit are regulated under a set of minimum standards for the establishment and operation of a narcotic treatment program pursuant to Texas Health and Safety Code, Chapter 466. Each facility shall be approved and monitored by the Texas Department of Health, Drugs and Medical Devices Division, 1100 West 49th Street, Austin, Texas 78756.

§229.142. Definitions. The following words and terms, when used in the sections of this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Administer - The direct application of a prescription drug by ingestion or any other means to the body of a patient by: a licensed practitioner, an agent of the practitioner, supervised by and under the order of the practitioner; or, the patient, at the direction of or in the presence of a practitioner.

(2) Agent - A pharmacist, registered nurse, licensed practical/vocational nurse, physician's assistant, or any other health care professional authorized by federal and state law to administer or dispense narcotic drugs.

(3) Approved narcotic drug - A drug approved by the United States Food and Drug Administration for maintenance and/or detoxification of a person physiologically addicted to opiate class of drugs.

(4) Approved narcotic drug permit - A permit issued by the Texas Department of Health to an applicant to operate a narcotic treatment program (NTP) which provides an approved narcotic drug for maintenance and/or detoxification and rehabilitative services to opioid addicted individuals.

(5) Approved to treat (ATT) - The maximum number of patients the NTP is allowed to treat at any point in time under the approved permit. This number is based on a maximum of 50 patients for each counselor employed by the program.

(6) Board's formal hearing procedures - The formal hearing procedures of the Texas Department of Health in Chapter 1 of this title (relating to Texas Board of Health) for conducting hearings on denial of application, suspension, or revocation of permit.

(7) Central registry - A process in which an NTP shall share patient identifying information about individuals who are applying for or undergoing detoxification or maintenance treatment on an approved narcotic drug to a central record system at the Texas Department of Health, Drugs and Medical Devices Division, Austin, Texas.

(8) Chemical dependency counseling - Face-to-face interactions between patients and counselors to help patients identify, understand, and resolve issues and problems related to chemical dependency.

(9) Chemical dependency counselor - A qualified credentialed counselor, as defined in Title 40, Texas Administrative Code (TAC), Chapter 150, or, counselor intern working under direct supervision of a licensed counselor or physician.

(10) Counselor intern (CI) - A person pursuing a course of training in chemical dependency counseling as defined in 40 TAC, Chapter 150.

(11) Department - The Texas Department of Health.

(12) DEA - Drug Enforcement Administration.

(13) Dispense - Preparing, packaging, compounding, or labeling for delivery a prescription drug in the course of professional practice to an ultimate user by or pursuant to the lawful order of a practitioner.

(14) FDA - Food and Drug Administration.

(15) Fee certificate - A document issued annually by the department after payment by the narcotic treatment program of the required fee based on the number of patients approved to treat.

(16) Hospital - A health care facility licensed by the department as a general hospital or a special hospital under the Health and Safety Code, Chapter 241; or a health care facility licensed by the Texas Mental Health and Mental Retardation as a private mental hospital under Health and Safety Code, Chapter 577; or a hospital directly operated under the authority of other statutes of the state.

(17) Medical director - A physician, licensed to practice medicine in the jurisdiction in which the program is located, who assumes responsibility for the administration of all medical services performed by the NTP, including ensuring that the program is in compliance with all federal, state, and local laws and regulations regarding the medical treatment of narcotic addiction with a narcotic drug.

(18) Medication unit - A facility established as part of, but geographically dispersed (i.e., separate) from a narcotic treatment program from which licensed private practitioners and community pharmacists are permitted to administer and dispense a narcotic drug, and are authorized to collect samples for drug testing or analysis for narcotic drugs.

(19) Narcotic drug - A drug as defined in Texas Controlled Substances Act, Health and Safety Code, §481.002(29)(A)-(D) and Title 42, Code of Federal Regulations (CFR), Part 8.

(20) Narcotic treatment program (NTP) - An organization which has been issued an approved narcotic drug permit by the department and the permit has not been suspended, revoked, or surrendered to the department.

(21) Person - An individual, corporation, organization, government or governmental subdivision, agency, business trust, partnership, association, or any other legal entity.

(22) Practitioner - As defined in Health and Safety Code, Chapter 481.

(23) Program director - An individual who provides overall administrative management to the NTP under guidelines established by the permit holder and the medical director.

(24) Program physician - A licensed physician who will provide medical treatment and counsel to the patients of an NTP under the supervision of the medical director.

(25) Program sponsor - A person named in the application for an NTP permit who is responsible for the operation of the narcotic treatment program and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

(26) Standing orders - Written instructions prepared by a licensed physician pursuant to the rules of the Texas State Board of Medical Examiners relating to standing delegation orders, as described in 22 TAC §§193.1-193.6, and shall be approved by the State Methadone Authority (SMA).

(27) State Methadone Authority (SMA) - The department, Drugs and Medical Devices Division.

(28) Status Report - An annual report submitted by the permit holder on a form provided by the department. The content of the report is determined by the department.

(29) SAMHSA - Substance Abuse and Mental Health Services Administration.

§229.143. Organization.

(a) Organization types. A narcotic treatment program (NTP) may be organized as an independent single program or may be a part of a centralized organization. Each location site must receive independent approval and, upon approval, be issued an approved narcotic drug permit. If an applicant is a partnership or a corporation, all individuals having a majority or management interest in such corporation or partnership must be identified.

(b) Persons responsible. Where two or more NTPs share a central administration (e.g., a city or statewide organization), the person responsible for the organization is required to be listed as the permit holder for each separate participating program. An individual shall indicate participation in the central organization at the time of the application. The permit holder may fulfill all recordkeeping and reporting requirements for these programs, but each program must continue to receive separate approval. If a physician assumes medical responsibility for more than one NTP, a statement describing how medical services will be provided to each NTP shall be submitted to the department.

(c) Medication unit. A program may establish a medication unit to facilitate the needs of patients who are stabilized on an optimal dosage level. A medication unit is limited to administering or dispensing a narcotic drug and collecting samples for drug testing or analysis for narcotic drugs in accordance with §229.148(h)(1). The only patients who shall be referred to a medication unit are those not in need of frequent counseling, rehabilitative, or other services. The physician shall be responsible for making this determination and documenting the patient's record. If a private practitioner wishes to provide other services besides administering or dispensing a narcotic drug and collecting samples for drug testing or analysis for narcotic drugs, he or she must submit an application for separate approval as an NTP.

§229.144. State and Federal Statutes and Regulations.

(a) A permit holder shall assure that the narcotic treatment program (NTP) is in compliance with all State of Texas laws and rules regulating chemical dependency treatment facilities including, but not limited

to, the following laws: Health and Safety Code, Chapters 464 and 466; the Medical Practice Act, Occupations Code, Chapters 151-165; the Nurse Practice Act, Occupations Code, Chapter 301; Licensed Vocational Nurses, Occupations Code, Chapter 302; the Texas Pharmacy Act, Occupations Code, Chapters 551-567; and the Licensed Professional Counselor Act, Occupations Code, Chapter 503.

(b) The permit holder shall assure that the NTP is in compliance with Title 42, Code of Federal Regulations, Part 8, titled, "Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction." To the extent that the Code of Federal Regulations conflicts with these sections, these sections shall prevail.

(c) All citations in these sections to statutes or regulations include those statutes or regulations as amended.

§229.145. Application, Fees, Permits.

(a) Application.

(1) A complete narcotic drug treatment application provided by the Texas Department of Health (department) must be submitted to the State Methadone Authority (SMA) to apply for an approved narcotic drug permit to operate a narcotic treatment program (NTP).

(2) A complete application filed in accordance with this subsection for an NTP will be reviewed and evaluated by the department, in accordance with §229.281 of this title (relating to Processing Permit Application Relating to Food and Drug Operation). An application shall not be considered complete until an application for an NTP has been submitted to the Drug Enforcement Administration (DEA), and to the Substance Abuse and Mental Health Services Administration (SAMHSA). If the program application is denied by the department, the applicant shall have an opportunity for a hearing pursuant to §229.147 of this title (relating to Denial of Application; Suspension or Revocation of Narcotic Drug Permit).

(3) A person acquiring an NTP currently operating under department approval must submit a new application in accordance with this subsection and an initial fee as required in subsection (b)(1) of this section. A narcotic drug permit will be issued to a new owner or new location and the permit issued to the previous owner or location shall be void and surrendered to the department by certified or registered mail within 24 hours following receipt of the new approved narcotic drug permit.

(4) Individuals who are currently chemical dependent and/or have a history of chemical dependency on any substances that are subjected to abuse within two years of application for a permit, are not eligible for ownership of an NTP.

(5) The number of patients that a clinic is approved to treat is in direct proportion to the number of counselors employed by that clinic. This proportion is a maximum of 50 patients for each counselor. The NTP may exceed the counselor to patient ratio on a temporary basis to permit hiring of new

staff when new admissions cause a ratio imbalance or when current staff leave and must be replaced.

(6) Applicants must provide to the department complete information for evaluation of criteria concerning location, funding, compliance history, and competency to operate an NTP.

(A) Scope. The department intends that new NTP locations be established to serve diverse patient populations without singular regard to proximity of location to an existing program(s). The department has established criteria to prevent competition for patients among NTPs in the same area that may result in increased noncompliance with state and federal regulations and compromised patient care.

(B) Criteria. An applicant must affirmatively demonstrate the following:

(i) serviceability of the program at the proposed location by providing the department the following:

(I) a map showing proximity of the proposed NTP to existing programs within a three-mile radius;

(II) a description of how the new program will ensure it will provide treatment services for an underserved population and not duplicate treatment services for existing patients in treatment at an established program in the area;

(III) copies of planned promotional materials, advertisements, and other techniques to publicize the proposed program; and

(IV) procedures that will be used to identify whether a patient is enrolled in another clinic;

(ii) the source and adequacy of financial assets necessary to operate the program;

(iii) if applicable, the compliance history of the applicant, which includes any issues reported to the department by SAMHSA, DEA or any other regulatory agency;

(iv) adequate planning and organizational structure demonstrated by full and complete answers submitted to all questions in the application materials; and

(v) a statement that the applicant has read, understood and agreed to follow all federal and state regulations concerning operation of an NTP.

(b) Fees and fee assessments.

(1) Initial fee. A nonrefundable initial fee of $700 must be submitted along with the complete application for the purpose of evaluation, inspection, and processing of the request to operate an NTP in accordance with subsection (a) of this section. An application will not be considered unless the application is accompanied by the initial fee. A nonrefundable initial fee of $100 shall be submitted for each medication unit requested in the initial application.

(2) Annual patient fee. Upon issuance of the permit, the permit holder shall submit a fee of $20 for each patient which the NTP is approved to treat no later than 30 days after the permit is issued. A fee certificate will be issued for a 12-month period from date of issuance of the permit. The current annual renewal patient fee certificate is transferable until its expiration date only in the following circumstances:

(A) to the permit holder of a program which relocates with no change of ownership; or

(B) to a new permit holder of a program which changes ownership at an existing location.

(3) Annual renewal fee and current status report. A nonrefundable annual renewal fee of $20 for each patient which the NTP is approved to treat shall be submitted by the permit holder to the department by filing a renewal form and current status report provided by the department prior to the expiration of the current fee certificate. A program that files a renewal fee after the expiration date must pay an additional delinquency fee of $3 per patient ATT. A program that files a current status report after the expiration date must pay a delinquency fee of $250. A fee certificate will be issued for a 12-month period from the expiration date.

(A) A fee of $20 per patient shall be submitted in the event the permit holder requests approval to increase the number of patients approved to treat during the current fee-paid year. In the calculation of the fee, temporary transfer patients shall not be considered as approved to treat patients by the program providing temporary treatment.

(B) An increase in the number of patients must be justified by demonstrating that the facility and staff are adequate to treat the increased number of patients.

(4) Medication unit fee. A nonrefundable annual renewal fee of $100 shall be paid for each medication unit the permit holder may operate.

(c) Permit.

(1) All NTPs, persons, or organizations are required by the Health and Safety Code, Chapter 466, to obtain an approved narcotic drug permit in order to provide treatment to patients with a

primary diagnosis of an opiate addiction.

(2) An approved narcotic drug permit shall be issued by the department subsequent to federal and state approval of an application as required in subsection (a) of this section, and payment of a fee as required in subsection (b)(1) of this section which will provide authorization to operate an NTP.

(3) Failure to pay the appropriate fee as required in subsection (b) of this section is grounds for suspension, revocation, or denial of a permit as provided in §229.147 of this title (relating to Denial of Application; Suspension or Revocation of a Narcotic Drug Permit).

(4) A permit issued by the department for the operation of an NTP is valid only for

the location of the NTP stated on the permit. A permit issued by the department is not transferable from one facility to another facility and must be surrendered to the department if the person holding the permit sells or otherwise conveys the facility to another person. If the permit holder sells or otherwise conveys the facility to another person or changes the location of the facility, a new application must be submitted as required in subsection (a) of this section and the fees must be paid as required in subsection (b) of this section. The previous permit must be surrendered to the department as specified in subsection (a)(3) of this section.

(5) A permit holder requesting to move an NTP to another location must submit a new application for a new permit as required in subsection (a) of this section, and pay the initial fee in accordance with subsection (b)(1) of this section. The previous permit must be surrendered to the department as specified in subsection (a)(3) of this section.

(6) An approved narcotic drug permit issued by the department shall remain in effect until suspended or revoked by the department or surrendered by the permit holder.

(7) The approved narcotic drug permit and the current certificate must be posted in a conspicuous location within the premises of the NTP.

(8) Methadone, or any other drug approved by the FDA for the treatment of opiate addiction, are the only drugs which shall be used in NTPs for patients with opiate addiction.

§229.146. Failure to Comply.

(a) The Texas Department of Health (department) may take any action provided in the Texas Health and Safety Code (code), Chapter 466, including emergency orders when it appears that a person violated, is violating, or is threatening to violate the code, these sections, or an order or permit issued pursuant to the code.

(b) If an emergency order is issued to suspend or revoke the permit of a narcotic treatment program

(NTP), the department may notify other NTPs to expect patients so that treatment services for the patients are maintained.

(c) The department will assess administrative or civil penalties in accordance with the provisions in §229.261 of this title (relating to Assessment of Administrative or Civil Penalties).

§229.147. Denial of Application; Suspension or Revocation of a Narcotic Drug Permit.

(a) Failure to comply with Chapter 466 or any of these sections shall be grounds for denial, suspension, or revocation of a narcotic drug permit.

(b) The commissioner may refuse an application for a license or may suspend or revoke a license if the applicant or licensee:

(1) has been convicted of a felony or misdemeanor that involves moral turpitude;

(2) is an association, partnership, or corporation and the managing officer has been convicted of a felony or misdemeanor that involves moral turpitude;

(3) has been convicted of a felony or misdemeanor in a state or federal court for the illegal use, sale or transportation of narcotic drugs, barbiturates, amphetamines, or any other dangerous or habit-forming drugs;

(4) is an association, partnership, or corporation and the managing officer has been convicted of a felony or misdemeanor in a state or federal court for the illegal use, sale, or transportation of narcotic drugs, barbiturates, amphetamines, or any other dangerous or habit-forming drugs;

(5) has had a permit to operate a narcotic treatment program denied, revoked, surrendered, and/or suspended by the Texas Department of Health (department), Drug Enforcement Administration (DEA), Food and Drug Administration (FDA), and/or Substance Abuse and Mental Health Services Administration (SAMHSA); or

(6) has obtained or attempted to obtain a license by fraud or deception.

(c) If it appears that an applicant or permit holder has failed to achieve or demonstrate compliance with these sections, the applicant or permit holder shall be given written notice of the denial, suspension, or revocation of the permit and an opportunity for a hearing in accordance with the department's formal hearing procedures in Chapter 1 of this title (relating to Board of Health), prior to taking any actions except for Emergency Orders under Health and Safety Code, §466.041.

(d) An applicant or permit holder may request one informal reconsideration conference with the

department prior to the requesting or setting of an administrative hearing under this chapter. The request for such an informal reconsideration may be in addition to the request for a formal hearing and will not waive the person's right to a formal hearing if the outcome of the informal reconsideration is adverse to the person. Requests for the informal reconsideration conference shall be addressed as provided in subsection (e) of this section.

(e) If the applicant or permit holder requests a hearing or informal reconsideration, he/she shall so notify, in writing, the Texas Department of Health, Drugs and Medical Devices Division, 1100 West 49th Street, Austin, Texas 78756, within 15 days of receipt of the notice provided in subsection (c) of this section. If the applicant or permit holder does not request a hearing or reconsideration within the specified time in the notice, then the applicant or permit holder shall be presumed to have agreed with the denial of the application, or suspension or revocation of the permit as stated in the notice.

(1) The request for a hearing and/or informal reconsideration shall:

(A) indicate the name(s) of the person(s) who will represent the applicant or permit holder; and

(B) include an explanation of the specific point(s) that are being disputed.

(2) Regarding the informal reconsideration conference, the department will contact the applicant or permit holder in writing or orally to discuss a mutually agreeable time and place for the meeting.

(3) The department may orally advise the applicant or permit holder of their decision relative to the informal hearing, with written confirmation to follow.

(f) The department may take action under emergency orders of the Health and Safety Code, Chapter 466, to immediately suspend an approved narcotic drug permit when approval is withdrawn from the permit holder by the SAMHSA or a registration is revoked by the DEA. The suspension shall be effective until the permit is surrendered, revoked, or reinstated in accordance with the department's formal hearing procedures in Chapter 1 of this title.

§229.148. State Operational Requirements.

(a) Management and administration.

(1) Human resources management.

(A) The narcotic treatment program (NTP) shall employ a sufficient number of qualified personnel to fulfill the service objectives of the program and to satisfy the intent of this section.

(B) Each NTP shall notify the State Methadone Authority (SMA) within seven days, in writing, of any change in the employment status of any of its program personnel. For new hires, the employee's home address and telephone number, copies of a current Texas driver's license and verification of professional licensure shall be provided with this notification. In addition, copies of a curriculum vitae, physician permit, Drug Enforcement Administration (DEA) certificate, and Texas Department of Public Safety registrations shall be provided for physicians. Notice of change of medical director or program sponsor must be given prior to the change or on the date the change occurs.

(C) Employees who are currently or formerly addicted to drugs of abuse and/or opiates (including methadone); or alcohol within two years; are considered risks to the security of drug stocks and shall not have access to the drug stocks or to the drug dispensing area.

(D) The NTP shall develop job descriptions for all staff members which include job duties and responsibilities, dates of regular review for continuing appropriateness, and documentation that the descriptions are provided to the individual staff member.

(2) Program operations.

(A) Each NTP shall provide medical and rehabilitative services and programs. These services should normally be made available at the primary facility, but the program sponsor may enter into a formal documented agreement with private or public agencies, organizations, or institutions for these services if they are available elsewhere. The program sponsor, in any event, must be able to document that medical and rehabilitative services are fully available to patients. Any service not furnished at the primary facility is required to be listed in any application for program approval submitted to the SMA. The addition, modification, or deletion of any program service is required to be reported immediately to the SMA.

(B) Each program must notify the SMA in writing of clinic closure due to holidays, training, and emergencies.

(C) Each program must provide a written response to a warning letter issued by the SMA within 15 days of the receipt of the letter.

(D) Each program must be able to provide observed daily dosing six days a week

(3) Patients' rights and grievance procedures.

(A) Each program shall develop and implement written policies regarding the patients' rights that include the following:

(i) the right to receive a written copy of these rights, which include the address and telephone number of the department, prior to admission;

(ii) the right to a humane environment that provides reasonable protection from harm and appropriate privacy for personal needs;

(iii) the right to be free from physical and verbal abuse, neglect and exploitation;

(iv) the right to be treated with dignity and respect;

(v) the right to be informed about the individualized plan of treatment and to participate in the planning, as able;

(vi) the right to be promptly and fully informed of any changes in the plan of treatment;

(vii) the right to accept or refuse proposed treatment;

(viii) the right to have personal information and medical records kept private;

(ix) the right to make a complaint and receive a fair response from the facility within a reasonable amount of time; and

(x) the right to complain directly to the department.

(B) Each program shall have a written grievance procedure for patients and others to present complaints, either orally or in writing, and to have their complaints addressed and resolved as appropriate in a timely manner.

(C) Each program shall maintain documentation of grievances and complaints and the resolution in the patient's file.

(b) Facilities and clinical environmental.

(1) Each facility shall have adequate and appropriate space and equipment to meet the objectives of the program and the needs of each person receiving services.

(2) Each facility shall be in compliance with all applicable local health, safety, sanitation, building and zoning requirements.

(3) All buildings and grounds must be constructed, maintained, repaired and cleaned so that they are not hazardous to the health and safety of the patients and staff.

(4) The patient medication area must be physically separate from the waiting area.

(5) Counseling areas, bathrooms, and medical examination areas must be designed to ensure patient privacy.

(c) Risk management.

(1) Each program shall develop and maintain a written plan to ensure the continuity of patient treatment in the event that an emergency or disaster disrupts the program's functions. This plan shall include a requirement for a program representative to notify the department of the disruption in function.

(2) The NTP sponsor must report to the department any patient death. The program shall report orally and in writing within two weeks of the program's knowledge of the death. A detailed account of any adverse reaction to an approved narcotic drug will be maintained in the patient treatment record.

(3) Security of drug stocks.

(A) Any theft, break-in, or diversion of drug stocks from the clinic must be reported to the SMA within 48 hours of discovery of the event.

(B) Adequate security is required to be maintained over drug stocks, and over the manner in which it is administered or dispensed. The program is required to meet the security standards for the distribution and storage of controlled substances as required by the DEA, Department of Justice (21 CFR 1301).

(4) Staff shall complete an incident report for all significant patient incidents including, but not limited to: violation of patients' rights, accidents and injuries, medical emergencies, behavioral and psychiatric emergencies, medication errors, medication adverse events, diversion, illegal or violent behavior, loss of a patient record, and release of confidential information without patient consent. The treatment facility shall ensure full documentation of the event is placed in the patient file; prompt investigation and review of the situation surrounding the event; implementation of timely and appropriate corrective action; and ongoing monitoring of any corrective actions until all corrections have been made.

(d) Professional staff credentials and development.

(1) Each program shall have and follow written policies and procedures for training program staff. A minimum of 12 clock hours of training or instruction must be provided annually for each staff member who provides treatment or services to patients. Such training must be in subjects that relate to the employee's assigned duties and responsibilities. Programs shall maintain records that each staff member has received the required annual training and be able to present copies of these records to the department upon request.

(2) The program sponsor shall:

(A) be a licensed health care professional or qualified credentialed counselor or have worked in the field of substance abuse a minimum of three years;

(B) have at least one year in the management or administration of direct services to persons with substance abuse problems; and

(C) submit a list of educational levels and work experience to the SMA upon employment.

(3) A legal entity organized and operating under the laws of this state shall:

(A) have at least one year experience in the management or administration of direct services to persons with substance abuse problems;

(B) employ a program director that is a licensed health care professional or qualified credentialed counselor or have worked in the field of substance abuse a minimum of three years; and

(C) submit a list of educational levels and work experience for the program director to the SMA upon employment.

(4) Medical director.

(A) The medical director shall be licensed to practice medicine in Texas and in accordance with 22 Texas Administrative Code (TAC), Chapter 163, and shall have worked in the field of addiction medicine a minimum of two years.

(B) Programs that are unable to secure the services of a medical director who meets the requirements of subparagraph (A) of this paragraph may apply to the SMA for a variance. The SMA has the discretion to grant such a variance for the two years experience in the field of addiction medicine when there is a showing that:

(i) the program has made good faith efforts to secure a qualified medical director, but has failed;

(ii) the program can secure the services of a licensed physician who is willing to serve as medical director and participate in an in-service training plan;

(iii) the program has developed an in-service training plan which is acceptable to the SMA;

(iv) the program has obtained the services of a medical consultant who meets the requirements of subparagraph (A) of this paragraph above and will be available to oversee the in-service training of the medical director and the delivery of medical services at the program requesting the variance.

(5) Physicians.

(A) The program physician(s) other than the medical director shall be licensed to practice medicine in Texas and in accordance with 22 TAC, Chapter 163, and shall have worked in the field of addiction medicine a minimum of one year.

(B) Programs that are unable to secure the services of a physician who meets the requirements of subparagraph (A) of this paragraph regarding the 1 year experience in the field of addiction medicine may apply to the SMA for a variance. The SMA has the discretion to grant such a variance when there is a showing that:

(i) the program has made good faith efforts to secure a qualified physician, but has failed;

(ii) the program can secure the services of a licensed physician who is willing to serve as program physician and participate in an in-service training plan;

(iii) the program has developed an in-service training plan which is acceptable to the SMA; and

(iv) the program employs a qualified medical director who has the experience and credentials specified in paragraph (3)(A) of this subsection or has completed the in-service training program specified in paragraph (3)(B) of this subsection.

(6) Counseling staff shall meet the requirements of a qualified credentialed counselor or counselor intern in Texas as defined in 40 TAC, Chapter 150, unless exempted.

(7) Nursing staff shall be licensed to practice in Texas and in accordance with 22 TAC, Chapter 217 or 22 TAC, Chapter 235.

(8) Pharmacists shall be licensed to practice in Texas and in accordance with 22 TAC, Chapter 283.

(9) Other health care professionals must be licensed in Texas and in accordance with applicable Texas state regulations.

(e) Patient admission and assessment.

(1) Voluntary participation. The person responsible for the program shall ensure that:

(A) a patient voluntarily chooses to participate in a program;

(B) all relevant facts concerning the use of the narcotic drug used by the program are clearly and adequately explained to the patient;

(C) all patients, with full knowledge and understanding of its contents, sign an informed written consent to treatment; and

(D) a parent, legal guardian, or responsible adult designated by the state authority (e.g., "Emancipated minor laws") consents in writing for the treatment of patients under the age of 18.

(2) Screening. All applicants for admission must be initially screened by a health care professional certified or licensed in accordance with applicable Texas state regulations to determine eligibility for admission. No applicant may be processed for admission until it has been verified that he or she meets all applicable criteria, and that the sources and methods of verification have been recorded in the applicant's file. The screening process must include:

(A) verification, to the extent possible, of an applicant's identity including name, address, date of birth, and other identifying data;

(B) history of narcotic dependence, evidence of current physiologic dependence, and a physical examination;

(C) medical history, including HIV status, pregnancy, current medications (prescription and non-prescription), and active medical conditions;

(D) patient history including, but not limited to, psychological and sociological background, educational and vocational achievements, and current mental status exam; and

(E) determination if the applicant needs special services and determination that the program is capable of addressing these needs either directly or through referral.

(3) Exceptions.

(A) Pregnant patients, regardless of age, who have had a documented opiate dependency in the past and who may return to opiate dependency may be admitted to treatment and placed on a maintenance regimen. For such patients, evidence of current dependence on opiates is not

needed if a program physician certifies in writing the pregnancy and finds treatment to be medically justified. Pregnant patients are required to be given the opportunity for, and should be encouraged to access prenatal care either by the program or by referral to appropriate health-care providers.

(B) A person who has resided in a penal or chronic care institution for one month or longer may be admitted to maintenance treatment within six months after release from such an institution without documented evidence of opiate dependency, provided the person would have been eligible for admission prior to incarceration or institutionalization, and the admission is medically justified. The medical justification must be documented in the patient's record.

(C) Applicants under 18 years of age are required to have had two documented attempts at short-term detoxification or drug-free treatment to be eligible for maintenance treatment. No person under 18 years of age may be admitted to a maintenance treatment program unless a parent, legal guardian, or responsible adult designated by the state authority completes and signs an informed written consent form. A person under 18 years of age shall not be given an initial dose of narcotic drug until the results of the admission drug test for drugs of abuse are reviewed by the physician. All documents must be kept in the patient's record.

(D) Under certain circumstances, a patient who has been treated and later voluntarily detoxified from comprehensive maintenance treatment may be readmitted to maintenance treatment without evidence to support findings of current physiologic dependence, up to two years after discharge, if the program attended is able to document prior narcotic drug comprehensive maintenance treatment of six months or more, and the admitting program physician, in his or her reasonable clinical judgment, finds readmission to comprehensive treatment to be medically justified. For patients meeting these criteria, the quantity of take-home medication, if take-home medication is permitted for the narcotic drug, will be determined in the reasonable clinical judgment of the program physician, but in no case may the quantity of take-home medication be greater than would have been allowed at the time the patient voluntarily terminated previous treatment. The admitting program physician or a program employee under supervision of the admitting program physician must enter in the patient's record documented evidence of the patient's prior treatment and evidence of all decisions and criteria used relating to the admission of the patient and the quantity of take-home medication permitted. The admitting program physician shall date and sign these entries in the patient's record or review the health-care professional's entries therein before the program administers any medication to the patient. In the latter case, the admitting program physician shall date and sign the entries in the patient's record made by the health-care professional within 72 hours of administration of the initial dose to the patient.

(4) Assessment. Each patient admitted to the program must be evaluated by the medical director or program physician and clinical staff who have been determined to be qualified by education, training, and experience to perform such assessments. The purpose of such assessments shall be to determine whether maintenance treatment, detoxification, or drug free treatment will be the most appropriate treatment modality for the patient. The evaluation must include an assessment of the patient's

needs for other services including, but not limited to, medical, psychosocial, educational, and vocational. A signed and dated statement by the program physician, that he or she has reviewed all documented evidence to support a one year history of opiate dependence and current opiate dependence, and that in his or her reasonable clinical judgment, the applicant fulfills the requirements for admission to the program is required to be recorded in the patient's file prior to the administration of an any narcotic drug to the patient.

(5) Transfer of patients.

(A) The admitting program shall obtain from the patient an authorization for disclosure of confidential information, pursuant to 42 CFR, §§2.31-2.34, for the purpose of obtaining accurate and current information concerning the patient's treatment at the former program.

(B) The program physician or an appropriately trained health care professional supervised by the admitting program physician shall consider data obtained from the transferring program that verifies the amount of time the patient has spent satisfactorily adhering to the eight criteria found in subsections (i)(1)(A)-(H) of this section in determining if the patient may continue the same frequency of clinic attendance permitted at the former program immediately before transferring to the new program.

(C) The program physician shall not allow the patient to attend the clinic less frequently than the most recent schedule allowed at the former program unless:

(i) copies of the patient's records are obtained to sufficiently document the patient's satisfactory adherence to federal and state regulations for the required time in treatment; and

(ii) the physician has completed an evaluation of the patient that includes consideration of the eight criteria in subsections (i)(1)(A)-(H) of this section and the additional criteria for attendance as found in 42 CFR, §8.12(i).

(D) At a minimum, an agent of the practitioner from the admitting program shall document in the patient file and an agent of the practitioner from the transferring program must provide the following information before the initial dose of narcotic drug is administered to a transfer patient:

(i) the last date and amount of narcotic drug administered or dispensed at the former program;

(ii) the length of time in continuous treatment;

(iii) the most recent record of clinic attendance;

(iv) the name, address, and telephone number of the program contacted;

(v) the date and time of the contact; and

(vi) the name of the program employee furnishing the information.

(E) Medical records.

(i) Patients who have had a physical examination and laboratory tests within the past three months may be admitted without a new physical examination and laboratory tests, unless the program physician requests it. The admitting program shall obtain copies of these results within 15 days of admission. If records are not obtained within 15 days, the program shall consider the patient a new patient and fulfill the minimum standards for admission.

(ii) The transferring program must supply patient medical records necessary to fulfill the requirements of paragraph (5)(B)-(D) of this section in response to a written request from the patient. The program shall furnish copies of medical records requested, or a summary or narrative of the records, including records received from a physician or other health care provider involved in the care or treatment of the patient, pursuant to a written consent for release of the information as provided by subparagraph (A) of this paragraph, except if the physician determines that access to the information would be harmful to the physical, mental, or emotional health of the patient, and the program may delete confidential information about another patient or family member of the patient who has not consented to the release. The information shall be furnished by the program within 15 days after the date of receipt of the request. If the program denies the request, in whole or in part, the program shall furnish the patient a written statement, signed and dated, stating the reason for the denial. A copy of the statement denying the request shall be placed in the patient's record.

(F) Fees. The transferring program responding to a request for medical records shall be entitled to receive a reasonable fee for providing the requested information. A reasonable fee shall be a charge of no more than $25 for the first 20 pages and $.15 per page for every page thereafter. In addition, a reasonable fee may include actual costs for mailing, shipping, or delivery. The program providing copies of requested medical records or a summary or a narrative of such records shall be entitled to payment of a reasonable fee prior to release of the information, unless the information is requested by a licensed Texas health care provider for purposes of emergency or acute medical care. In the event the program receives a proper request for copies of medical records or a summary or narrative of the medical records for purposes other than for emergency or acute medical care, the program may retain the requested information until payment is received. In the event payment is not routed with such a request, the program shall notify the requesting party in writing of the need for payment and may withhold the information until payment of a reasonable fee is received. A copy of the letter regarding the need for payment shall be made part of the patient's medical record. Medical records requested pursuant to a proper request for release may not be withheld from the patient, the patient's authorized agent, or the patient's designated recipient for such records based on a past due account for medical care or treatment previously rendered to the patient.

(6) For record keeping purposes, if a patient misses appointments for two weeks or more without notifying the clinic, the episode of care is considered terminated and is to be so noted in the patient's record. An exception determination would be in circumstances where the patient can provide documentation of continuation of care. The documentation must be maintained in the patient's record. This does not mean that the patient cannot return for care. If the patient does return for care and is accepted into the program, the patient is considered a new patient and is to be so noted in the patient's record. Cumulative time spent by the patient in treatment is counted toward the number of years of treatment, provided there has not been a continuous absence of 90 days or more.

(7) Dual enrollment. There is a danger of drug dependent persons attempting to enroll in more than one NTP to obtain quantities of drugs for the purpose of self-administration or illicit marketing. Therefore, drugs shall not be provided to a patient who is known to be currently receiving drugs from another treatment program without prior approval from the SMA. Patients who are known to be enrolled in more than one NTP at a time will be forced to choose one clinic for treatment. That patient must then begin treatment as a completely new patient, including attending the clinic on a daily basis or a minimum of six days per week, for a period of six months.

(8) Medical Evaluation. Each patient is required to have a medical evaluation by a program physician or an authorized health-care professional under the supervision of a program physician on admission to a program. A patient is required to have a face-to-face meeting with the program physician no later than one week after admission. A patient readmitted within three months after discharge does not require a repeat physical examination unless requested by the program physician. The admission medical evaluation must be documented in the patient's record and shall include at a minimum:

(A) a medical history including the required history of opiate dependence;

(B) evidence of current physiologic and/or psychologic dependence unless excepted under sections (e)(3)(A)-(D);

(C) investigation of the organ systems for possibilities of infectious disease, pulmonary, hepatic, and cardiac abnormalities, and dermatologic sequelae of addiction;

(D) examination of the patient's general appearance, head, ears, eyes, nose, throat (thyroid), chest (including heart, lungs, and breasts), abdomen, extremities, skin, and neurological assessment;

(E) determination of the patient's vital signs (temperature, pulse, blood pressure, and respiratory rate); and

(F) the program physician's overall impression of the patient.

(9) Intradermal tuberculosis test.

(A) Programs shall follow the Mantoux technique, using 0.1 ml of purified protein derivative (PPD) tuberculin containing five tuberculin units (TU) injected into the volar surface of the forearm.

(B) Reaction to the Mantoux test shall be read by a trained health care worker 48 to 72 hours after the injection.

(C) Results should be recorded in millimeters (mm) in the patient's record.

(D) Patients who had negative tuberculin skin tests on admission must be retested each year and results recorded in the patient's record.

(E) Patients with a positive skin test must have further diagnostic evaluation as designated by the Centers for Disease Control and Prevention (CDC).

(F) Documented verification of follow-up on all patients referred for tuberculosis evaluation must be placed in the patient's record.

(G) Patients with previously positive PPD shall not be retested. The program shall obtain verification of diagnostic evaluation and therapeutic follow-up, including preventive treatment or treatment of tuberculosis. The patient shall be referred for further evaluation if disposition cannot be verified. Documentation of the above shall be placed in the patient's record.

(H) Immuno-suppressed populations shall be evaluated periodically as indicated to rule out active tuberculosis, particularly after contact with persons known to be infectious. HIV-infected persons with a positive tuberculin skin test (equal to or greater than 5 mm of indurations) should have a chest x-ray and be evaluated by a clinician to rule out active tuberculosis. HIV-infected individuals who have symptoms suggestive of tuberculosis shall be referred for chest x-ray and clinical evaluation regardless of their tuberculin skin test status.

(10) Minimum required laboratory tests. All biological samples must be analyzed by a laboratory approved under the Clinical Laboratory Improvement Amendments (CLIA) and all applicable Texas state standards. For those tests requiring a blood sample, if in the reasonable clinical judgment of the program physician, a patient's subcutaneous veins are severely damaged to the extent that a blood specimen cannot be obtained, the lab tests may be omitted; however, an attempt to perform the required laboratory tests must be made annually or the patient must be referred to a medical facility that is able to draw blood. The following tests must be performed and documented:

(A) CBC and differential;

(B) routine and microscopic urinalysis;

(C) liver functions profile (SGOT, SGPT); and

(D) serological test for syphilis.

(11) Short-term detoxification. A patient may be admitted to short-term detoxification regardless of age. The program physician shall document in the patient record the reason for admitting the patient to short-term detoxification. Take-home medication is not allowed during short-term detoxification. A history of one year opiate dependence is not required for admission to short-term detoxification. No test or analysis is required except for the initial drug screening test, and a tuberculin skin test. The initial treatment plan and periodic treatment plan evaluation required for comprehensive maintenance patients are not necessary for short-term detoxification patients. A primary counselor must be assigned by the program to monitor a patient's progress toward the goal of short-term detoxification and possible drug-free treatment referral. The narcotic drug is required to be administered daily by an agent authorized by the physician in reducing doses to reach a drug-free state over a period not to exceed 30 days. All other requirements of comprehensive maintenance treatment shall apply.

(12) Long-term detoxification. A patient may be admitted to long-term detoxification regardless of age. The narcotic drug is required to be administered daily in reducing doses to reach a drug-free state over a period not to exceed 180 days. The patient is required to be under observation while ingesting the drug at least six days a week. Initial and random monthly drug screening tests must be performed on each patient. Initial and monthly treatment plans are required. All other requirements of comprehensive maintenance treatment shall apply.

(13) Denial of admission. If in the reasonable clinical judgment of the medical director a particular patient would not benefit from treatment with a narcotic drug, the patient may be refused such treatment even if the patient meets the admission standards.

(f) Treatment planning.

(1) Initial treatment plan. The primary counselor shall enter in the patient's record the counselor's name, the contents of the patient's initial assessment, and the initial treatment plan. The primary counselor shall make these entries immediately after the patient is stabilized on a dose or within four weeks after admission, whichever is sooner. The initial treatment plan is required to contain a statement that outlines:

(A) realistic short-term treatment goals which are mutually acceptable to the patient and the program;

(B) behavioral tasks a patient must perform to complete each short-term goal;

(C) the patient's requirements for education, vocational rehabilitation, and

employment;

(D) the medical psychosocial, economic, legal, or other supportive services that a patient needs;

(E) the frequency with which these services are to be provided and/or the source to which the patient will be referred to receive the necessary services; and

(F) the treatment plan must be signed and dated by the primary counselor and the patient.

(2) Periodic treatment planning. The program physician or primary counselor shall review, reevaluate, and alter where necessary each patient's treatment plan at least once each 90 days during the first year of treatment, and at least twice a year thereafter. The treatment plan must be signed and dated by the primary counselor and the patient. At least once a year, the program physician shall review the treatment plan documented in each patient's record, and ensure that each patient's progress or lack of progress in achieving the treatment goals is entered in the patient's record by the primary counselor.

(3) The program supervisory counselor or physician shall review and countersign all treatment plans formulated by counselor interns.

(4) Counseling sessions. Frequency and content of counseling sessions with patients shall be in keeping with patient needs and modality of treatment.

(g) Approved narcotic drugs.

(1) Methadone. The program medical director or program physician shall prescribe methadone in accordance with 42 CFR, §8.12(h)(3-4). If opiate abstinence symptoms are not suppressed, the physician may administer additional methadone, within a scope that ensures patient safety, and taking into consideration the pharmacokinetic properties of the methadone. The medical director shall take into consideration the drug manufacturer's dosing instructions and current best practices when prescribing and administering. Methadone shall be administered or dispensed in oral form only when used in an outpatient treatment program. Hospitalized patients under care for a medical or surgical condition are permitted to receive methadone in parenteral form when the attending physician judges it advisable. All forms of methadone shall be dispensed in such a way as to reduce its potential for parenteral abuse and to differentiate it from other narcotic drugs (i.e., contrasting color and taste), unless prior SMA approval is obtained.

(2) Levo-alpha acetyl methadol (LAAM). The program medical director shall prescribe LAAM in accordance with drug manufacturer's dosing instructions and current best practices.

(3) A narcotic drug may be administered or dispensed only by an agent of the practitioner.

The licensed practitioner assumes responsibility for the amounts of narcotic drugs administered or dispensed and shall record and countersign all changes in dosage schedules. If the program keeps the record of administration and dispensing of narcotic drugs separate from the patient's file, the program shall transfer data from the dosing record to the patient's file at least monthly.

(h) Testing for licit and illicit drug use. The physician shall ensure that test results are not used as the sole criterion to force a patient out of treatment, but are used as a guide to change treatment approaches. The program shall ensure that when test results are used, presumptive laboratory results are distinguished from results that are definitive.

(1) Drug abuse tests. Analysis of such tests shall be performed in a laboratory approved under the Clinical Laboratory Improvement Amendments (CLIA) and all applicable Texas state standards.

(A) The program shall ensure that an initial drug test or analysis is performed for each new patient, including permanent transfer patients, before the initial or maintenance dose is administered, and at least monthly random tests or analyses are performed on each patient in comprehensive maintenance treatment for the initial year of treatment and eight random drug abuse tests yearly thereafter. When a sample is collected from each patient for such test or analysis, it must be done in a manner that minimizes opportunity for falsification.

(B) The program must have and follow written procedures for the screening of test samples for licit and illicit drugs. The procedures shall describe in sufficient detail a plan for collection, storage, handling and analysis of test samples. The procedures shall further describe the program's response to test results that include at least the following:

(i) training for staff members of the importance and relevance of reliable and timely drug abuse test procedures and reports, the purpose of conducting drug abuse tests, and the significance of the results;

(ii) a protocol for collection of test samples that minimizes the opportunity for falsification and incorporates the elements of randomness and surprise;

(iii) storage of test samples in a secure place to avoid substitution;

(iv) a requirement for disclosure of test sample results to the patient and documentation in the patient record of program and patient response to the test results; and

(v) if a patient refuses to provide a test sample, that shall be considered the same as a positive result for illicit drugs. Such refusals shall be documented in the patient record.

(C) Each sample must be analyzed for opiates, methadone, methadone metabolite,

amphetamines, cocaine, barbiturates, and benzodiazepines. In addition, if any other drug or drugs have been determined by a program to be abused in that program's locality, or as otherwise indicated, each sample must be analyzed for any of those drugs as well. If a program proposes to change a laboratory used for such testing or analysis, the program shall notify the SMA in writing and provide copies of any contracts or agreements.

(2) Prescription Medications. The patient record shall contain adequate documentation of any prescription drug, other than methadone, that a patient may be taking, including the name of the drug, the prescription number, the dose, the reason for prescribing, the name of the prescribing doctor, the pharmacy's name and telephone number, the date it was prescribed, and the length of time the patient is to be taking the drug.

(i) Unsupervised use.

(1) The program physician shall comply with 42 CFR, §8.12(i) regarding the dispensing of take-home doses of medication. The program physician shall adhere to the following criteria in determining whether a patient is responsible in handling narcotic drugs:

(A) absence of recent abuse of drugs (opioid or non-narcotic), including alcohol;

(B) regularity of clinic attendance;

(C) absence of serious behavioral problems at the clinic;

(D) absence of known recent criminal activity;

(E) stability of the patient's home environment and social relationships;

(F) length of time in comprehensive maintenance treatment;

(G) assurance that take-home medication can be safely stored within the patient's home; and

(H) whether the rehabilitative benefit to the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion of narcotic drugs.

(2) Take-home protocol. Regardless of time in treatment, a program physician may deny or rescind the take-home medication privileges of a patient if any of the eight criteria found in subsections (i)(1)(A)-(H) of this section are not met.

(3) Treatment program decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in 42 CFR, §8.12(i)(1) shall be determined by the medical director

or program physician only. In any event, a patient may not be given an additional supply of narcotic drugs beyond their current unsupervised use without prior written approval from the SMA.

(4) Packaging. Take-home medication must be packaged in special packaging as required by 16 CFR, §1700.14 in accordance with the Poison Prevention Packaging Act (Pub. L. 91-601, 15 U.S.C., 1471 et seq.) to reduce the chances of accidental ingestion.

(5) Labeling. The take-home medication must be labeled with the following:

(A) Clinic name, address, and telephone number;

(B) The word "METHADONE" in larger capital letters;

(C) The phrase "Date Dispensed" or "Dispensed On";

(D) The phrase "To Be Taken On";

(E) Client's name;

(F) Physician's name;

(G) Label should contain some warning similar to the following:

(i) "WARNING: This drug may be FATAL to any person other than to whom prescribed";

(ii) "Law Prohibits Transfer To Any Person Other Than For Whom Prescribed"; and

(H) Mixing and diluting directions in accordance with its approved product labeling.

(6) Patients must provide a secure storage container for all take-home medications.

(j) Discharge from treatment.

(1) Voluntary discharge. If a patient decides to discontinue treatment, the program shall ensure that the patient receives medical withdrawal or appropriate transfer or referral. The program shall not try to keep a client in treatment by coercion, intimidation or misrepresentation.

(2) Involuntary discharge and termination from treatment. Involuntary discharge from treatment is an action of last resort. Involuntary discharge occurs in response to behavioral problems where a threat to the well-being of the program, staff, or other patients outweighs the potential risk of harm to the

individual patient.

(3) Discharge against medical advice. The patient has the right to discontinue treatment when he or she chooses to do so. The program shall explain the risks of leaving treatment. The physician, or agent of the practitioner, shall have a face-to-face consultation with the patient. The physician shall determine the schedule for withdrawal from opiate maintenance therapy to ensure humane withdrawal. The program shall document the issue that caused the patient to seek discharge, and shall provide full documentation in the patient's record of steps taken to avoid discharge.

(4) Other types of discharge. Discharge for non-payment of fees, serious non-compliance, or other reasons shall be determined by the program physician only. The physician, or agent of the practitioner, shall have a face-to-face consultation with the patient. The physician shall determine the schedule for withdrawal from opiate maintenance therapy to ensure humane withdrawal and shall document the reason for the discharge in the patient's record.

(k) Record keeping and documentation.

(1) Patient records.

(A) The medical director or authorized physician shall sign or countersign and date all records within 72 hours of the occurrence of the action or order. The documents that require signature include, but are not limited to: all medical orders, changes in medical orders, changes in dosage schedule, changes in dose, exceptions to mandatory take-home schedule, the rationale for allowing exceptions to the mandatory take-home schedule, review of the eight point criteria prior to altering a schedule of take-home medication, exceptions due to special circumstances, findings from
the admission medical evaluation, exceptions to the minimum requirements for admission into treatment, all admission evaluations performed by health care professionals, all medical evaluations performed by health care professionals, yearly treatment plans, initial medical orders, and any other record required by the SMA.

(B) All patient records must be maintained in a secure room, locked file cabinet, safe or other similar container when not in use; and, accessibility shall be limited to staff
directly involved in patient care.

(C) The program shall ensure that accurate records traceable to specific patients are maintained showing dates, quantity, and batch or code marks of the drug dispensed. These records must be retained for a period of three years from the date of dispensing. An adequate record must be maintained for each patient. The record is required to contain a copy of the signed consent, the date of each visit, the amount of drug administered or dispensed, the results of each test or analysis for drugs, any significant physical or psychological disability, the type of rehabilitative and counseling efforts employed, an account of the patient's progress, and other relevant aspects of the treatment program. For recordkeeping purposes, if a patient misses appointments for two weeks or more without notifying the program, the episode of care is

considered terminated and is to be so noted in the patient's record. This does not mean that the patient cannot return for care. If the patient does return for care and is accepted into the program, this is considered a readmission and is to be so noted in the patient's record. In calculating the number of years of comprehensive maintenance treatment, the period is considered to begin on the first day the medication is administered, or on readmission if a patient has had a continuous absence of 90 days or more. Cumulative time spent by the patient in more than one program is counted toward the number of years of treatment, provided there has not been a continuous absence of 90 days or more.

(D) Confidentiality.

(i) The program must comply with the provisions of 42 CFR, Part 2, and all applicable Texas statutes and regulations, governing confidentiality of patient records.

(ii) The program shall implement a written policy to protect client records and other client identifying information from loss, tampering, and unauthorized access or disclosure.

(iii) The program shall limit access to the records to staff with job duties requiring their use.

(iv) The staff shall keep records locked at all times unless an authorized person is continuously present in the immediate area.

(v) The staff shall have an effective tracking system and shall ensure that each record is returned to the file at the end of each day or shift.

(vi) A treatment program or medication unit or any part thereof, including any facility or any employee, shall permit a duly authorized employee of SAMHSA or the department to have access to and to copy all records on the use of narcotic drugs in accordance with the provisions of 42 CFR, Part 2.

(E) All notations by NTP personnel on patient files and other files kept by the NTP for purposes of this chapter shall be typed, printed, or legibly handwritten so that any regulatory authority can read the writing.

(F) An NTP may not refuse to allow an inspection or otherwise interfere with personnel of the SMA in the performance of their duties, including the photocopying of patient records during an inspection. It is a violation for an NTP not to fully cooperate in any inspection by the SMA.

(2) Records on the receipt, storage, and distribution of narcotic medication are subject to inspection under federal and Texas controlled substances laws.

(3) Personnel records shall contain results of annual tuberculosis testing. Each employee

working in an NTP must receive an intradermal skin test using the Mantoux technique at the start of employment and annually thereafter. Programs shall follow the Mantoux technique, using 0.1 ml of purified protein derivative (PPD) tuberculin containing five tuberculin units (TU) injected into the volar surface of the forearm. Reaction to the Mantoux test shall be read by a trained health care worker 48 to 72 hours after the injection. Results should be recorded in millimeters (mm) and documented in the employee's file. Employees who had negative tuberculin skin tests at the start of employment must be retested each year and results recorded in the employee's file. Employees with a positive skin test must have further diagnostic evaluation as designated by the Centers for Disease Control and Prevention (CDC). Documented verification of follow-up on all employees referred for tuberculosis evaluation must be placed in the employee's file. Employees with previously positive PPD shall not be retested. The program shall obtain verification of diagnostic evaluation and therapeutic follow-up, including preventive treatment or treatment of tuberculosis. The employee shall be referred for further evaluation if disposition cannot be verified. Documentation of the above shall be placed in the employee's file.

(4) Personnel records shall also contain a job description, employment application, verification of credentials, evidence of a current driver's license, job performance evaluation completed annually and reviewed with the individual, and any other information required by law.

§229.149. Inspections and Monitoring.

In order to determine compliance with the sections in this chapter and related statutes, the department may enter and inspect the location of an applicant or a permit holder at any reasonable time without prior notification. The monitoring may include inspection of relevant records and/or interviews with patients and narcotic treatment program (NTP) personnel to determine compliance with the rules and statutes governing the operation of an NTP. Inspection and monitoring are subject to the provisions of the Code of Federal Regulations, Title 42, Part 2.

§229.150. Central Registry.

(a) The permit holder shall participate in the central registry for the purpose of sharing patient identifying information as requested by the department to prevent multiple enrollment of patients in narcotic treatment programs (NTPs).

(b) A narcotic drug shall not be provided to a patient who is known to be currently enrolled in another NTP except when the patient is a temporary transfer patient.

(c) The patient shall always report to the same NTP unless prior approval is requested by the parent NTP's program physician or program director for the patient to receive treatment as a temporary transfer patient at another NTP. In any event, a patient may not be authorized more than two weeks away from their home clinic without prior approval from the State Methadone Authority (SMA).

(d) A central registry shall be established by the department which shall maintain a record of the

patient's identification and the NTP to which each patient is enrolled. Information shall be maintained in accordance with confidentiality requirements in the Code of Federal Regulations, Title 42, Part 2, and Title 42, §8.12(g).

(e) Each NTP shall report to the central registry specific information.

(1) The following changes in patient status: new patient, readmitted to the same clinic, admitted from another NTP as a permanent transfer patient, transferred to another narcotic maintenance or detoxification program, deceased patient, or discharged (terminated) from maintenance or detoxification treatment shall be identified and reported to the central registry located at the Texas Department of Health, Drugs and Medical Devices Division, by telephone, electronic mail, or facsimile on the day the action occurs and written documentation must be submitted within a 24-hour period (or the next state working day immediately following weekends or holidays).

(2) Each NTP's verbal and written report to the central registry shall identify and provide the following information for each patient:

(A) name, address, and telephone number of the NTP, and approved narcotic drug permit number;

(B) date action was taken (MO-DA-YR);

(C) action taken identified as:

(i) new patient, readmitted patient (NP);

(ii) terminated patient (TP);

(iii) permanent transfer-in patient (TIP);

(iv) permanent transfer-out patient (TOP); or

(v) deceased patient (DP); and

(D) patient identification as follows:

(i) Upon admission, the patient must be identified with a current Texas state driver's license, United States passport, military identification card, or Texas state-issued identification card containing a photograph of the patient or other identification approved by the SMA. If a patient is not able or willing to furnish the required documents, the program shall contact the SMA within 72 hours to access the Central Registry to check for possible duplicate enrollment and to discuss acceptable, alternate forms of identification. Photocopies of each of these documents must be maintained in the patient's record. The

program shall document in the patient's file attempts to induce the patient to obtain state identification.

(ii) An identification number shall be constructed using the following code numbers for the patient:

(I) color of eyes: Brown (1), Blue (2), Green (3), Hazel (4), Gray (5), and Other (6);

(II) date of birth stated in number digits with two digits for the month, day, and year (example: January 9, 1953--010953);

(III) gender: male (1) and female (2); and

(IV) race: White (1), Black (2), Hispanic (3), Asian (4), American Indian (5), and Other (6).

(iii) An example of a patient identification number in accordance with clause (ii) of this subparagraph for a patient with blue eyes, date of birth--January 9, 1953, male, and white is 201095311. Patients with the same identification code will be assigned an alphabetical extension by the SMA (for example 201095311A, 201095311B, etc.).

§229.151. Approved Hospital Narcotic Drug Detoxification Treatment.

(a) Application.

(1) The hospital administrator must submit a complete hospital narcotic drug detoxification treatment application provided by the department, a copy of federal form SMA -162 filed with the Substance Abuse and Mental Health Services Administration (SAMHSA), and a copy of federal form DEA 363 filed with the Drug Enforcement Agency (DEA), to apply for an approved narcotic drug permit for inpatient narcotic drug detoxification.

(2) The hospital administrator shall submit to the department the name of the individual (e.g., pharmacist) responsible for receiving and securing supplies of narcotic drugs for the treatment of narcotic addicts. The individuals responsible for supplies of narcotic drugs must be authorized to do so by federal or state law.

(3) The hospital administrator shall submit to the department a general description of the hospital including the number of beds, specialized treatment facilities for drug dependence, and nature of patient care undertaken.

(4) The hospital pharmacist shall submit to the department the quantity of narcotic drugs anticipated to be used per year for narcotic addiction detoxification treatment.

(5) A member of the hospital medical staff shall be named by the administrator or chief of medical staff as the responsible physician for the narcotic drug detoxification treatment.

(6) A hospital pharmacy registered by the Texas State Board of Pharmacy must be registered as a narcotic treatment program (NTP) for detoxification by the DEA.

(7) A complete application filed in accordance with this subsection for an NTP will be reviewed and evaluated by the department in accordance with §229.281 of this title (relating to Processing Permit Applications Related to Food and Drug Operations). Denial of application shall be in accordance with §229.147 of this title (relating to Denial of Application; Suspension or Revocation of a Narcotic Drug Permit).

(b) Fees.

(1) A nonrefundable initial fee of $200 must be submitted for each location or each owner with the application for an inspection, evaluation, and processing of the application. An application will not be considered unless the application is accompanied by the initial fee.

(2) The nonrefundable annual renewal fee of $200 shall be submitted by the permit holder to the department by filing a renewal form provided by the department prior to the expiration of the current fee certificate. A program that files a renewal fee after the expiration date must pay an additional $100 as a delinquency fee. A fee certificate will be issued for a 12-month period from the expiration date. The department may not issue a permit if the current permit has been suspended, revoked, or surrendered by the permit holder.

(3) A status report must be submitted to the department along with the annual renewal fee. A program that files a current status report after the expiration date must pay a delinquency fee of $250.

(c) Permit.

(1) A hospital providing treatment to patients with a primary diagnosis of opiate addiction must apply for and be issued an approved narcotic drug permit by the department which shall remain in

effect until suspended or revoked by the department or surrendered by the permit holder.

(2) An approved narcotic drug permit authorizing the hospital to operate a narcotic drug detoxification treatment program shall be issued subsequent to federal and state approval of the application as required in subsection (a) of this section, and payment of the fee as required in subsection (b) of this section.

(3) Failure to pay the fee as required in subsection (b) of this section is grounds for denial of the application, suspension, or revocation of the permit as provided in §229.147 of this title (relating to Denial of Application; Suspension or Revocation of a Narcotic Drug Permit).

(4) A hospital must be licensed as a chemical treatment facility under Health and Safety Code, Chapter 464, or have received an exemption from licensure standards from the Texas Commission on Alcohol and Drug Abuse.

(5) A permit issued by the department for the operation of an approved narcotic drug detoxification treatment program in a hospital applies both to the hospital owner and to the place where the hospital is to be located. A permit issued by the department is not transferable from one facility to another facility and must be surrendered to the department if the person holding the permit sells or otherwise conveys the facility to another person.

(6) If the permit holder sells or otherwise conveys the facility to another person or changes the location of the facility, a new application must be submitted as required in subsection (a) of this section and fees must be paid as required in subsection (b) of this section. When an approved narcotic drug permit is issued to a new permit holder or new location, the permit issued to the previous permit holder and/or location shall be revoked without hearing and must be surrendered to the department by certified or registered mail within 24 hours following receipt of the new approved narcotic drug permit.

(7) The approved narcotic drug permit and the current fee certificate must be posted in a conspicuous location within the premises of the NTP.

(8) Methadone, or any other drug approved by the United States Food and Drug Administration for the treatment of opiate addiction, are the only drugs which shall be used in hospital inpatient detoxification treatment of patients with opiate addiction.

§229.152. Federal Regulations.

The Texas Department of Health adopts by reference the federal regulations on "Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction" found in Title 42, Code of Federal Regulations, Part 8. A copy of these regulations is indexed and filed in the Drugs and Medical Devices Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756.

§229.153. Enforcement.

(a) Denial, Suspension or Revocation of Permit. Except for Emergency Orders under the Health and Safety Code, §466.041, after notice to an applicant or a permit holder and after the opportunity for a hearing, the department may:

(1) deny an application of the person if the person fails to comply with this chapter or the rules establishing minimum standards for the issuance of a permit adopted under this chapter; or

(2) suspend or revoke the permit of a person who has committed a Level I, II, or III violation as defined in subsection (d) of this section.

(b) Administrative Penalty. If a person violates this chapter, a rule adopted under this chapter, or an order or permit issued under this chapter, the commissioner may assess an administrative penalty against the person.

(c) Criteria for the assessment of administrative or civil penalties. Administrative penalties will be assessed in accordance with the following criteria:

(1) history of previous violations;

(2) seriousness of the violation;

(3) hazard to the health and safety of the public; and

(4) demonstrated good faith.

(d) Severity levels.

(1) Severity Level I, penalty of $7,500-10,000, covers violations that are most significant and have a direct negative impact on the public health and safety including, but not limited to, adulteration, misbranding, or false advertising that results in fraud.

(2) Severity Level II, penalty of $5,000-7,500, covers violations that are very significant and have an impact on the public health and safety including, but not limited to, adulteration, misbranding, or false advertising that results in fraud.

(3) Severity Level III, penalty of $2,500-5,000, covers violations that are significant and which, if not corrected, could threaten the public and have an adverse impact on the public health and safety including, but not limited to, adulteration, misbranding, or false advertising that results in fraud.

(4) Severity Level IV, penalty of $1,250-2,500, covers violations that are of more than minor significance, and if left uncorrected, would lead to more serious circumstances.

(5) Severity Level V, penalty of $500-1,250, covers violations that are of minor safety or fraudulent significance.

(e) Severity of a violation. The severity of a violation may be increased if the violation involves deception, fraud, or other indication of willfulness. In determining the severity of a violation, there shall be taken into account the economic benefit gained through noncompliance.

(f) Adjustments to penalties. The department may make adjustments to the penalties listed in subsections (e), (f), or (g) of this section for any one of the following factors.

(1) Previous violations. The department may consider previous violations. The penalty may be reduced or increased within the specified range of each severity level for past performance. Past performance involves the consideration of the following factors: whether the previous violation was identical or similar to the current violation; how recent the previous violation was; the number of previous violations; and the violator's response to previous violation(s) in regard to correction of the problem.

(2) Demonstrated good faith. The department may consider good faith effort(s) of the violator to correct the violations and demonstrate compliance with the department's rules and regulations as a basis to reduce the proposed penalty. The penalty may be reduced within the specified range of each severity level if good faith efforts to correct a violation have been, or are being made. The department on a case-by-case basis will determine good faith effort. All good faith effort(s) to comply with the department's rules and regulations must be fully documented by the violator to merit consideration from the department as to whether to reduce the proposed penalty.

(3) Hazard to the health and safety of the public. The department may consider the hazard to the health and safety of the public. The penalty may be increased within the specified range of each severity level when a direct hazard to the health and safety of the public is involved. It shall take into account, but need not be limited to, the following factors:

(A) whether any death(s), disease or injuries have occurred from the violation;

(B) whether any existing conditions contribute to a situation that could expose

humans to a health hazard;

(C) the impact that the hazard has on various segments of the population such as children, surgical patients, and the elderly; and

(D) whether the consequences would be of an immediate or long-range hazard.

(g) Hearings, appeals from, and judicial review of final administrative decisions under this section shall be conducted according to the contested case provisions of the Government Code, Chapter 2001, and the board's formal hearing rules found in Chapter 1 of this title.